

KY Hepatitis Connections

Greetings partners and colleagues! I am pleased to share with you the first issue of *KY Hepatitis Connections*. As the new KY Adult Hepatitis Program Coordinator, I believe it is imperative to create a legacy of working with partners and colleagues across the Commonwealth of Kentucky to prevent the transmission of viral hepatitis, particularly viral hepatitis caused by hepatitis A virus hepatitis B virus, and hepatitis C virus. The *KY Hepatitis Connections* will announce current information, opportunities for viral hepatitis continuing professional education and information about educational materials available for clinical and community settings. Your knowledge and input are greatly valued, as we are committed to keeping you up to date on shared progress in the medical community on viral hepatitis and its impact on our families throughout the Commonwealth. Follow us on Facebook: KY Viral Hepatitis.

Kathy Sanders, RN MSN

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Northern Kentucky sees spike in Hepatitis C rate

Feb. 3, 2013 - EDGEWOOD, Ky. (AP) — EDGEWOOD, Ky. (AP) — Statistics show cases of hepatitis C have exploded in northern Kentucky.

Due to the increase, the Independent Health Department District is offering free testing to anyone concerned about the chronic blood-borne disease that affects the liver. In addition, the department is encouraging high-risk groups to get tested.

The Kentucky Enquirer (http://bit.ly/YEXCR3) reports the area had 23 cases of acute hepatitis C in 2010, 42 in 2011 and 44 in 2012. Officials have said the heroin epidemic in the area is likely a factor in the increase.

"We are no longer surprised by the numbers because we have been seeing it rise for a few years now," said Patricia Burns, infection control coordinator for St. Elizabeth Healthcare hospitals. "I have to think it is related to the issues in NKY surrounding illegal, intravenous drug use."

Health department spokeswoman Emily Gresham Wherle said anyone who tests positive for the disease will be provided with counseling, education and care options. She says the health department also hopes to get a better understanding of the prevalence of the problem.

Counties included in the health district include Boone, Campbell, Kenton and Grant.

Jennifer Hunter, the health department's director of clinical services, said testing began last year and will continue through at least March. At that point, she said the Centers for Disease Control and Prevention will evaluate the results and determine whether the program should continue.

She said hepatitis C is usually transferred by sharing items to inject drugs, such as syringes.

"Almost 88 percent (of those tested) had a history of IV drug use," Hunter said.

Dr. Lynne Saddler, district director of health, attributed some of the increase to growing awareness, and encouraged those in risk groups to get tested and get treatment if needed.

"Obviously, these folks need to know what their status is and take appropriate actions in their own lives," Saddler said. "We all need to be sure we are reducing our risks."

Information from: The Kentucky Enquirer, http://www.nky.com

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Sounding the Alarm on a Silent Epidemic: Federal HIV/STD Advisory Group Adopts Viral Hepatitis as Priority

February 12, 2013

Antigone Dempsey, M.Ed.

In support of enhanced cross-government efforts to address the prevention, care and treatment of viral hepatitis, a federal advisory body on HIV and STDs recently expanded its scope and title to include viral hepatitis. Now known as the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC), the body advises the Secretary of Health and Human Services, Director of the Centers for Disease Control and Prevention (CDC), and Administrator of the Health Resources and Services Administration (HRSA) on objectives, strategies, policies and priorities for HIV, viral hepatitis and STD prevention and treatment efforts. The CHAC also supports the agencies' responses to the prevention and health service delivery needs of affected communities, and the needs of individuals living with or at risk for HIV, viral hepatitis and other STDs.

Members of the CHAC are appointed by the Secretary and are a diverse group of experts, including people living with HIV/AIDS, from backgrounds such as public health, migrant health, community-based organizations, clinical care, and national organizations. The CHAC meets twice yearly and accomplishes additional work between meetings through several workgroups.

Aware that viral hepatitis affects over 4 million Americans and is the leading cause of both liver cancer and transplantation, the CHAC was prompted to engage more actively in addressing this issue primarily by three things, according to CHAC's Co-chair, Dr. Jeanne Marrazzo, Professor of Medicine at the University of Washington. "The implementation of the Action Plan for the Prevention, Care and Treatment of Viral Hepatitis has really sharpened the focus of federal agencies on viral hepatitis and galvanized cross-agency collaborations. The unfolding of those efforts to increase testing, vaccinations, and access to care and treatment as well as improve education for providers and patients highlighted a natural opportunity for the CHAC to engage and lend our advice and support." A second main impetus was learning from CDC analysis last spring that mortality related to hepatitis C has now outpaced AIDS related deaths. Finally, the CHAC understood that HIV and hepatitis coinfection is a serious issue for providers and people living with HIV/AIDS. One-third of people living with HIV are co-infected with hepatitis B (HBV) or hepatitis C (HCV) and viral hepatitis progresses at a faster rate among persons with HIV. People living with HIV/AIDS and hepatitis experience greater liver-related health problems than non-HIV infected persons. Indeed, liver disease—much of which is related to hepatitis C and hepatitis B infection — has become a leading cause of death among people living with HIV/AIDS in the United States.

In an effort to effectively integrate viral hepatitis into its work, the CHAC first unanimously voted to change the name of the committee to include "viral hepatitis". In addition, CHAC's charter was officially changed to integrate activities related to viral hepatitis and we have recommended to the Secretary that upcoming vacancies on the CHAC be filled by persons with experience and expertise in viral hepatitis.

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As we have worked to integrate viral hepatitis into the work of the CHAC over the past nine months, these are some of the highlights:

- The CHAC established a Viral Hepatitis Workgroup to further the ongoing efforts of the committee to address this epidemic.
- The CHAC is working closely with federal and community partners to address the priorities of the
 Action Plan for the Prevention, Care and Treatment of Viral Hepatitis and other federal efforts,
 focusing on addressing patient and provider education, surveillance, testing, linkages to care, and
 research.
- The CHAC also recently endorsed CDC's recommendation for one-time HCV screening for persons born between 1945-1965.

With heightened awareness and new and more effective life-saving treatments available, now is the time to take important policy, research, program and service delivery actions that can positively impact the lives of people living with hepatitis B and C. The CHAC welcomes the opportunity to contribute to this national effort and invites others to join us in prioritizing efforts to better prevent and diagnose viral hepatitis and improve the care and treatment for those living with the disease. Our meetings are open to the public and always include time for public comment; the CHAC welcomes and invites community members to share their thoughts and concerns on these issues. Our meeting times and locations are published in the Federal Register.

Ms. Dempsey is the Area of Expertise Lead for HIV/AIDS at Altarum Institute &

APP FOR HEPATITIS

The Hepatitis C Physician eGuide mobile app: A free and useful tool for healthcare providers who treat with PEGASYS

The Hepatitis C Physician eGuide mobile app is a handy educational tool for your daily practice that is available for download to your iPhone or BlackBerry.

The Hepatitis C Physician eGuide provides

- PEGASYS treatment algorithm, including contraindication parameters
- Lab assessment scheduling tool
- Detailed safety information
- A convenient way to quickly contact your local Genentech PEGASYS representative regarding questions about PEGASYS and educational materials

**This app is not intended to replace your clinical judgment or to provide recommendations regarding chronic HCV diagnosis or dosing. It is intended for US healthcare providers only.

iPhone uses can download the Hepatitis C Physician eGuide application from iTunes.

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Transmission of hepatitis B virus from an orthopedic surgeon with a high viral load.

Abstract

BACKGROUND:

During the evaluation of a needle-stick injury, an orthopedic surgeon was found to be unknowingly infected with hepatitis B virus (HBV) (viral load >17.9 million IU/mL). He had previously completed two 3-dose series of hepatitis B vaccine without achieving a protective level of surface antibody. We investigated whether any surgical patients had acquired HBV infection while under his care.

METHODS:

A retrospective cohort study of all patients who underwent surgery by the surgeon was conducted. Patients were notified of their potential exposure and need for testing, and samples with positive HBV loads underwent DNA sequencing. Characteristics of the surgical procedures for the cohort were evaluated.

RESULTS:

A total of 232 (70.7%) of potentially exposed patients consented to testing; 2 were found to have acute infection and 6 had possible transmission (evidence of past exposure without risk factors). Genome sequence analysis of HBV DNA from the infected surgeon and patients with acute infection revealed genetically related virus (>99.9% nucleotide identity). Only age was found to be statistically different between those with confirmed or possible HBV transmission and those who remained susceptible to HBV.

CONCLUSIONS:

We documented HBV transmission during orthopedic surgery to 2 patients from a surgeon with HBV. This investigation highlights the importance of evaluating individuals who do not respond to 2 series of HBV vaccination, the increased risk of HBV transmission from providers with high viral loads, and the need to evaluate the clinical practice of providers with HBV and implement appropriate procedure-based practice restrictions.

Enfield KB, Sharapov U, Hall KK, Leiner J, Berg CL, Xia GL, Thompson ND, Ganova-Raeva L, Sifri CD.

Source:

Office of Hospital Epidemiology, University of Virginia Health System, Charlottesville, VA 22908-0473, USA.

PubMed: http://www.ncbi.nlm.nih.gov/pubmed/23074317

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New Phase III Interferon-Free Studies

—Alan Franciscus

Recently new interferon-free Phase 3 studies were announced. Joining the stellar line-up of HCV drugs in Phase 3 clinical development are Gilead and Boehringer Ingelheim.

Gilead

ION-1 was launched in October 2012 to test sofosbuvir/GS-5885 with and without ribavirin for a treatment duration of either 12 or 24 weeks. Sofosbuvir/GS-5885 is a fixed dose once-a-day pill. The trial is recruiting HCV Genotype 1 treatment-naïve patients.

ION-2 will recruit patients with HCV genotype 1 who did not achieve a sustained virological response or viral cure with a prior course of interferon or interferon plus protease inhibitor therapy.

- Fixed-dose of sofosbuvir, GS-5885 plus ribavirin for a treatment duration of 12 weeks, and
- Fixed-dose of sofosbuvir, GS-5885 with and without ribavirin for a treatment duration of 24 weeks

Gilead now has clinical trials with their lead candidates, sofosbuvir, GS-5885, with and without ribavirin and/or pegylated interferon in HCV genotype 1, 2, 3, and 4 patients. Gilead expects to file for Food and Drug Administration (FDA) approval mid-2013 for sofosbuvir, and in 2014 for GS-5885. Gilead is also studying sofosbuvir/GS-5885 with and without ribavirin for a treatment duration of 8 weeks for HCV genotype 1 treatment-naïve patients and 12 weeks for HCV genotype 1 treatment-experienced patients. These two Phase 3 studies will mean that Gilead now has 7 Phase 3 studies.

In these trials Gilead is studying a fixed dose which will mean a **very low pill burden** (possibly 1 combination pill of sofosbuvir/GS-5885—only once a day). This is compared to today's current standard of care treatment that requires taking many, many pills every 7 to 9 hours.

Boehringer Ingelheim (BI)

BI already has faldaprevir in combination with pegylated interferon plus ribavirin in Phase 3 studies. In January BI announced HCVerso 1 and HCVerso 2 clinical trials for HCV genotype 1b patients. The new studies announced will combine faldaprevir—120 mg (QD-once a day), BI 207127—600 mg (BID-twice a day) plus ribavirin (TID-three times a day). There will be three treatment arms:

HCVerso 1 (Treatment Naïve)

- Group 1 will be treated for 24 weeks of the study drugs (without placebo)
- Group 2 will receive 16 weeks of the study drugs and 8 additional weeks of placebo

Group 3 will include patients with compensated cirrhosis treated with the same combination and for 24 weeks (without placebo)

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HCVerso 2 (Treatment Naïve)

HCVerso 2 will also include patients who are ineligible for interferon

- Group 1—24 weeks of BI 207127, faldaprevir plus ribavirin
- Group 2—16 weeks of BI 207127, faldaprevir plus ribavirin—the first 8 weeks of treatment will be with a placebo drug
- Group 3—24 weeks of BI 207127, faldaprevir plus ribavirin—HCV patients with compensated cirrhosis will be recruited for this group

All in all, the future looks very bright for people with hepatitis C since there are now 8 HCV drugs in Phase 3 studies and the promise of an interferon-free therapy is even closer than ever to a realization. For more information about how to qualify for these and other studies visit www.clinicaltrials.gov

Continuing Education Opportunities:

NASTAD (National Alliance of State & Territorial AIDS Directors) has a Primer on Viral Hepatitis Policymaking and Programs at the Federal Level.

http://www.nastad.org/Docs/033247 NASTADPrimer web.pdf

Clinical Management of Hepatitis C in Patients With and Without HIV Coinfection

http://www.ceitraining.org/resources/audio-video-detail.cfm?mediaID=148&cme=1

Andrew Talal, MD, MPH

Associate Medical Director

Center for the Study of Hepatitis C at the Weill Cornell Medical College

Learning From HIV: Pharmacology's Role in the Management of Hepatitis C

http://www.ceitraining.org/resources/audio-video-detail.cfm?mediaID=149&cme=1

Charles Flexner, MD

Professor of Medicine and Pharmacology

Johns Hopkins University School of Medicine

New Insights in Hepatitis B and HIV Co-infection

http://www.ceitraining.org/resources/audio-video-detail.cfm?mediaID=147&cme=1

Marion Peters, MD

ACTG Hepatitis Transformative Science Group

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Perinatal Hepatitis B Prevention Program



Perinatal Hepatitis B virus (HBV) infection is classified as any infant aged 1-24 months of age with HBsAg positivity that was born in the US or US territories to an HBsAg —positive woman. The goal of the KY Perinatal Hepatitis B Prevention Program (PHBPP) is to prevent mother to baby transmission of HBV by identifying and giving hepatitis B immunoprophylaxis to all infants born to women who are HBsAg-positive. This will help to reduce the risk of chronic hepatitis B infection for the infant. Infants who become infected with HBV at birth have a 90% chance of developing life long, chronic infection and premature death.

All pregnant women should be screened for HBsAg during every pregnancy. All positive results need to be reported to the local health department (LHD) so the LHD can assure the mother gets education and the infant gets proper treatment to prevent perinatal HBV infection. If a pregnant woman presents for delivery without HBsAg screening, the testing should be done at that time.

Identification is the first step in protecting these infants. Please help protect these infant and preform HBsAg testing on all pregnant women. Also, report positive results to the LHD and to the nursing staff caring for this infant so proper treatment can be given to prevent perinatal HBV infection. Should you have any questions, contact Julie Miracle at Julie.Miracle@ky.gov.

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"People use drugs, legal and illegal, because their lives are intolerably painful or dull. They hate their work and find no rest in their leisure. They are estranged from their families and their neighbors. It should tell us something that in healthy societies drug use is celebrative, convivial, and occasional, whereas among us it is lonely, shameful, and addictive. We need drugs, apparently, because we have lost each other. Wendell Berry



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